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Ralph E. Jocke

Patent

Trademark Law

January 17, 2006

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Attn: Art Unit 3653  
Patent Examiner Michael E. Butler

Re: **Appeal Nos. :** 2005-0064 and 2003-1769  
**Application No.:** 09/014,076  
**Confirmation No.:** 4092  
**Filed:** January 27, 1998  
**Applicants:** Max Fedor, et al.  
**Title:** Method for Tracking and  
Dispensing Medical Items  
**Docket No.:** D-1056 DIV3

Sir:

Please find enclosed Applicants' Response to the Request for Information dated  
December 19, 2005 for filing in the above case.

No fee is deemed required. However, the Commissioner is authorized to charge any  
necessary fee associated with this Response and any other fee due to Deposit Account 10-0637.

Very truly yours,

Ralph E. Jocke  
Reg. No. 31,029

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Ralph E. Jocke  
330 • 722 • 6446  
FACSIMILE

rej@walkerandjocke.com  
E-MAIL

231 South Broadway, Medina, Ohio U.S.A. 44256-2601



D-1056 DIV3

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appeal Nos.: <b>2005-0064 and 2003-1769</b>	)	
	)	
In re Application of:	)	
<b>Max Fedor, et al.</b>	)	Art Unit 3653
	)	
Application No.: <b>09/014,076</b>	)	
	)	
Confirmation No.: <b>4092</b>	)	Patent Examiner
	)	Michael E. Butler
Filed: <b>January 27, 1998</b>	)	
	)	
Title: <b>Method For Tracking And Dispensing Medical Items</b>	)	

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Request for Information ("Action") dated December 19, 2005, kindly  
enter Appellants' remarks without prejudice as follows:

The Action includes a Request for Information pursuant to 37 CFR § 1.105 ("Request").

As best understood, the Action requests:

- I. "an affidavit from each inventor specifying which claim(s) each respective inventor is a sole or co-inventor of the claimed material."
- II. "identify the claimed elements of claim 38 in the evidence submitted."
- III. "identify date confirmatory elements of the evidence submitted."
- IV. comments in support of the sufficiency of the 37 CFR § 1.131 declaration submitted 8/30/2000.

The Request is improper

Appellants respectfully submit that the Request is improper because the information requested is not reasonably necessary to properly examine or treat a matter in the current application. All of the requested information pertains to the 37 CFR § 1.131 declaration filed 8/30/2000 (hereinafter "Declaration"). However, additional information is not needed by the Examiner in order to make a decision on the Declaration. Conversely, as evidenced by the record, the Declaration was already fully considered and determined sufficient by the Examiner (without the requested information). Furthermore, since the requested information would not be part of the already filed declaratory evidence, it is unclear what impact it could possibly have on the distinct Declaration. Again, the requested information is not necessary.

Does the Examiner need the requested information to make a decision on the sufficiency of the Declaration? The answer is no. Again, any newly submitted information would not be a part of the original Declaration, and thus would have no bearing thereon. The Examiner doesn't

need any additional information to make a decision on the Declaration, especially in light of the fact that the Declaration was already fully considered and deemed to be sufficient by the Examiner.

Furthermore, the Office is required to make a decision on a 37 CFR § 1.131 declaration based on the facts at hand (e.g., MPEP 715, 715.08), not on information requested years later. Information that would be submitted after the fact should have no influence on the Office's original position regarding the Declaration. The Office has not explained how the requested information would change the fixed evidence set forth in the Declaration. Again, the requested information is not necessary. Nor does the Office need additional information to vacate its previous position on the Declaration (and reopen prosecution). The Request is unreasonable as it has no value or merit regarding the Declaration or the examination of the Application.

The facts of record show that the Office already had enough information (and doesn't need any more information) to make a legal determination regarding the effectiveness of the submitted Declaration. The issues currently pending are fixed and prosecution is closed. Unless the Office (on the record) reverses its position regarding sufficiency of the Declaration, which would require reopening prosecution, then no request for additional information is proper.

Review on the merits of a 37 CFR § 1.131 declaration is by appeal to the Board of Patent Appeals and Interferences ("Board"). However, Appellants respectfully submit that the sufficiency of the Declaration is not an issue which they have appealed, nor should it be part of the current appeal. To the contrary, the Declaration has already been determined by the Office to be sufficient. It follows that the Declaration is solely a matter between the Board and the Examiner.

**I.** The information requested to be submitted is unknown and/or is not readily available to the party or parties from which it was requested. As the record shows, this application is a divisional of application 08/361,783 which was filed (12/16/1994) over eleven years ago. Application 08/361,783 was also a CIP of Application 08/186,285 filed 1/25/1994, which in turn was a CIP of Application 08/009,055 filed 1/25/1993.

The current application has had at least three different assignees, as evidenced by the (attached) Patent Assignment Abstract of Title. It has been determined that none of the inventors are currently employed by the (original) assignee of the Application at the time of filing or by any of the subsequent assignees, or the current assignee. Some of the inventors may be employed by a competitor of the current assignee. In other words, to ascertain the whereabouts of all the inventors, let alone easily obtain an affidavit from each (which may aid their competitor), would be extremely difficult (if it is even possible). Would the PTO be willing to let a current examiner submit an affidavit that supports an applicant, but that is detrimental to interests of the PTO?

It is therefore stated that the information requested cannot be submitted because it is unknown and/or is not readily available at the present time.

**II.** What constitutes the mentioned "evidence submitted" in the Action is unclear. Appellants presume that it is the body of the Declaration. Hence, an identification (which is not a full listing) of the features in *method* claim 38 with regard to the Declaration is shown below (all citations are to locations in the Declaration).

**Claim 38**

*A method for tracking and dispensing medical items comprising the steps of:*

"method for tracking and dispensing medical items" (e.g., page 2, line 7).

"tracks" and "dispensing" (e.g., Exhibit page 7).

"Track Inventory Utilization" (beginning at Exhibit page 16).

*placing at least one unit of a plurality of types of medical items in a plurality of storage locations,*

"The data base . . . was programmed with data corresponding to a plurality of types of medical items, and a plurality of storage locations in which the types of medical items were stored" (page 3, lines 10-12).

"After selecting the storage locations for each of a plurality of types of medical items, I input to the data store information on each medical item and its associated storage location" (page 3, lines 16-18).

"type of supply and initial quantity assigned to each register, medicine dispenser . . . entered manually" (e.g., Exhibit page 13).

Figure 1.5-2b regarding Supply Position (Exhibit page 30).

"Assign Supplies to Positions" (e.g., Exhibit page 64).

*wherein each storage location holds only one type of medical item at a time;*

"Only one type of medical item was placed in each storage location" (page 6, lines 4-7).

"A supply position may contain exactly one supply type. It may contain many supplies of the same supply type" (e.g., Exhibit page 45, lines 4-5).

*inputting patient identifying data to a data entry device, wherein the patient identifying data corresponds to a patient;*

"I also included in the database, data corresponding to identifying data for each of a plurality of patients" (page 4, lines 1-2). "The patient data was input through the Administrator's Workstation" (page 4, lines 5-6).

"Patient identifying data was then input through a data entry device. I did this through the touch screen on the display terminal of the system" (page 9, lines 13-14).

"Create Patient Profile" (e.g., process 21 at Exhibit page 16).

Patient data (Exhibit Figure 1.5-2a on page 29; page 42; page 60).

*removing one unit of a type medical item from a storage location with a dispenser mechanism;*

"These medical item providing devices included a dispenser from which selected medical items could be dispensed in response to electrical signals" (page 4, lines 20-22).

"I then operated the system so that one unit of a type of medical item was removed from a storage location with a dispenser mechanism" (page 10, lines 1-3).

"1. Select" and "1. Dispense" (e.g., Exhibit pages 75-77).

*modifying a data store using a processor in operative connection with the data store,*

"This system included a database server computer which was a PC running a type 486 processor. The computer had an associated data store . . . database . . . that . . . included data" (page 2, line 15 to page 3, line 2).

Data entry (e.g., Exhibit page 60).

Administrator's Workstation; Data Base Server; Graphical User Interface; and Display Terminal (e.g., Exhibit Appendix, pages 109 and 111).

*wherein the processor is in operative connection with the data entry device and the dispenser mechanism,*

"This system included a database server computer which was a PC running a type 486 processor. The computer had an associated data store" (page 2, lines 15-16).



"The . . . medication dispenser in my system were all connected by wiring connections to the display terminal. The display terminal was connected to the database server computer. The Administrator's Workstation, through which the data about users, patients, medication, storage locations and other information was input to the database, was also connected to the database server computer. As a result each of these components was operatively connected in a system network as described" (page 7, lines 12-19).

"User Interfaces" (e.g., Exhibit page 59; Exhibit Appendix, pages 109 and 111).

*wherein the data store includes data representative of the patient and data representative of the type medical item stored in the storage location,*

"I also included in the database, data corresponding to identifying data for each of a plurality of patients" (page 4, lines 1-2).

"include in the data store, data representative of a plurality of patients for whom the medical items could be taken from the system" (page 8, lines 6-7).

"I input to the data store information on each medical item and its associated storage location" (page 3, lines 17-18).

"database included data representative of each of the storage locations in the medical item providing devices, and the particular type of medical item that I had placed in each storage location" (page 8, lines 1-3).

Figure 1.3-4 (e.g., Exhibit page 15).

"Create Patient Profile" (e.g., process 21 at Exhibit page 16).

Patient data (Exhibit Figure 1.5-2a on page 29; page 42; page 62).

Figure 1.3-3 regarding "types of supplies," "quantities" and "storage assignments" (Exhibit page 12).

Figure 1.5-2b regarding Supply Position (Exhibit page 30).

Enter data for patients and medical item storage locations (e.g., Exhibit page 60).

"Assign Supplies to Positions" (e.g., Exhibit page 64).

*and wherein the data store is modified responsive to the removing step and the inputting step, to include data representative of the dispense of the type medical item for the patient.*

"Once the selected patient data was input, I then operated the system so that one unit of a type of medical item was removed from a storage location with a dispenser mechanism" (page 10, lines 1-3).

"In operation of my system, after I had . . . selected a patient and a medical item, and had removed the selected type medical item from the storage

location, the . . . computer operated . . . to modify the data in the data store. The data was modified to include data which represented the dispense of the selected type medical item held in the storage location from which the medical item had been removed. The data was also modified . . . to include data representing that the type medical item had been taken for the selected patient" (page 10, line 20 to page 11, line 6). "showed that a record of the removal of the selected type medical item for the selected patient was present in the data store" (page 12, lines 1-2). "Inventory changes are determined automatically by . . . medicine dispensers" (e.g., Exhibit page 11, process 1; Figure 1.3-3). "Supplies dispensed by a Medicine Dispenser are automatically updated" (e.g., Exhibit page 14, line 8). "The Patient Usage form displays supplies that were taken . . . against a patient's account" (e.g., Exhibit page 79, lines 1-2).

It is respectfully submitted that the Declaration fully proves actual reduction to practice of the claimed invention prior to March 7, 1994. Nevertheless, even if the Declaration were not fully commensurate with the subject matter of claims 38 and 48, the Declaration would still overcome the rejection if any "differences" between the recited invention (of claims 38 and 48) and what is shown in the Declaration "would have been obvious to one of ordinary skill in the art" (MPEP § 715.02). "Such evidence is sufficient because applicants' possession of what is shown carries with it possession of variations and adaptations which would have been obvious, at the same time, to one of ordinary skill in the art." Accordingly, it is respectfully submitted that

even if the Declaration (which includes the Exhibit) was not fully commensurate with the recited claims, the Office still must consider whether declarant had reduced to practice a novel arrangement which would have been sufficient enough to have rendered the claimed invention (of claims 38 and 48) obvious to one of ordinary skill in the art. In this situation it is clear that the Declaration proves entitlement to an invention date that is prior to March 7, 1994.

**III.** What constitutes the mentioned "evidence submitted" in the Action is unclear. As previously mentioned, Appellants presume that it is the body of the Declaration.

What is meant by "identify date confirmatory elements of the evidence submitted" is unclear. Appellants respectfully submit a declarant is not required nor is it necessary to identify actual dates in a 37 CFR § 1.131 declaration (MPEP 715.07 (II)), especially in establishing an actual reduction to practice. Diligence is not an issue. The Declaration shows that the invention recited in claims 38 and 48 was completed, tested, and successfully operated (i.e., actual reduction to practice) prior to 3/7/1994. For example, note Declaration page 2, lines 4-5 and numbered paragraph 6. Since an *actual reduction* to practice occurred prior to the date mentioned, diligence (or actual dates) is not an issue.

**IV.** The Office has invited Appellants to provide arguments on behalf of the Examiner that rebut the Board's preliminary assessment of the Declaration. As previously mentioned, the sufficiency of the Declaration is solely an affair between the Board and the Examiner. However, in order to comply with the Request, some arguments showing the validity and legal sufficiency of the Declaration follow.

Appellants respectfully request that the Board make a decision on the claim rejections which have been appealed. The sufficiency of the Declaration is not part of Appellants' appeal. Furthermore, the PTO examining corps has already reconsidered the Declaration on the merits and again found that the Declaration is legally sufficient. It follows that the sufficiency of the Declaration (which is not an issue between the Examiner and Appellants) should not be an issue before the Board.

Furthermore, this application has been subject to three remands. The Examiner's position regarding the sufficiency of the Declaration has consistently remained firm. Thus, it appears that any future remands regarding the Declaration would only needlessly delay prosecution. The Board has cited no authority for ordering the Examiner to make a new rejection. Thus, there appears to be a stalemate with the Appellants caught in the middle. If the Board continues to disagree with the position of the Examiner then it has recourse under 37 CFR § 41.50(b). The Appellants continue to await decision on the real issues from which their appeal was taken.

**The Declaration is valid and legally sufficient**

Appellants agree with the Examiner that the 35 CFR § 1.131 Declaration is sufficient in establishing an earlier date. The Examiner provided a clear, convincing, and well-written

explanation for this sufficiency at section IV in the Office Action dated 9/15/2004. Appellants respectfully submit that the Board misinterprets both the Declaration by Mr. McGrady and the explanation set forth by the Examiner. The Board's implied criticism of the Declaration is unfounded, as explained in more detail hereafter.

Claims 38-53 are the only claims pending. One would understand that the Declaration states (in numbered section 2) that Mr. McGrady is a joint inventor of the subject matter described in claims 38-53 when they are taken together as a whole. That is, he is not the inventor of all claims, but rather one of the inventors in the application. The Examiner correctly recognized and acknowledged this stated association at page 4, first paragraph, in the Office Action dated 9/15/2004.

One would understand that the Declaration further states (in numbered section 3) that Mr. McGrady is the sole inventor of claims 38 and 48. The Examiner also correctly recognized and acknowledged this stated fact at page 4, second paragraph, in the Office Action dated 9/15/2004. Numbered sections 2 and 3 in the Declaration are consistent with each other and do not conflict.

The Remand dated 9/15/2005 ("Remand") alleges (on page 2) that "(1) the declaration was made by only one of the joint inventors of the subject matter claimed, a circumstance deemed to be troubling in light of the declarant's many references to 'my' invention and activities which 'I' performed and the lack of any specific mention of the contributions of the other joint inventors."

Appellants respectfully submit that there is nothing wrong with having a declaration by less than all named inventors of an application. 37 CFR § 1.131 permits a declaration to be signed by less than all of the inventors. The Board's attention is directed to MPEP 715.04(I)(B).

Mr. McGrady is the sole inventor of claims 38 and 48. Hence, the Declaration was properly signed only by Mr. McGrady. How can the other inventors (associated with other claims) be a signatory to a declaration to claims of which they are not an inventor or know the facts associated therewith?

The Remand (on page 2) also alleges that "(2) the declaration was not accompanied by any evidence documenting the asserted activities leading to the alleged reduction to practice or a satisfactory explanation for the absence of such evidence".

As best understood, the Remand implies that a showing of "diligence" is absent in its reference to "evidence *documenting* the asserted activities leading to the alleged reduction to practice". However, diligence is not an issue here, nor does it need to be shown.

There are three ways to show prior invention (MPEP 715.07 (III)). Mr. McGrady shows an *actual reduction* to practice (pertaining to claims 38 and 48) prior to the effective date mentioned in the Declaration. With an actual reduction to practice prior to the date at issue, a showing of diligence is not needed. How can diligence to completion be shown after an actual reduction to practice (including the completion) has already occurred? Nor does diligence have to be shown from the time of the actual reduction to practice to a constructive reduction to practice (i.e., an application filing). The Board's attention is also directed to MPEP 715.07(III)(A), 2138.01(II), and 2138.05.

The Remand asserts that "the declaration was not accompanied by any evidence documenting the asserted activities leading to the alleged reduction to practice". Appellants respectfully submit that this is not a requirement for establishing prior invention. One having ordinary skill in the art would recognize that the SelecTrac Functional Specification document in combination with the Declaration provides ample support for establishing an actual reduction to practice of the subject matter of claims 38 and 48 prior to the effective date. The document is essentially a "blueprint" for one skilled in the art (e.g., document page 5, line 2).

The Remand (at footnote 1) alleges that the submitted document proffered in conjunction with the declarant's assertion of a conception of the claimed invention (Declaration paragraph 5a), does not, and is not asserted to, constitute proof of the stated activities. The Appellants respectfully disagree. A 37 CFR § 1.131 declaration itself is a *prima facie* assertion of proof of the activities stated therein. Regardless, as previously discussed, a declarant need not show a path of activities (diligence) from conception to actual reduction to practice. A declarant (as in the current situation) only needs to show the actual reduction to practice.

The Remand's reference to "conception" in Declaration paragraph 5a is unclear. Every invention starts at a conceived idea. Likewise, paragraph 5a states "having *previously* conceived of the idea of a system and method for tracking an dispensing medical items."

Although not needed, the Declaration together with the document outlines the activities carried out leading to the actual reduction to practice. Furthermore, it should be understood that the "Specification" referred to in the Declaration is not the Application's specification but rather the SelecTrac Functional Specification document, as indicated in paragraph 5a.




The Examiner's apology in the current Action (at paragraph number 4) in reference to the "nine months" statement is not necessary. Note the statement in the Office Action dated 9/15/2004 at page 5, last paragraph. Also note the Remand at footnote 2. The Examiner's reference to a date in the statement being nine months earlier than a priority date of Appellants' is accurate. The date (3/7/1994) sworn behind in the Declaration is nine months earlier than the priority date (12/16/1994) of Appellants parent application 08/361,783. As previously discussed, application 08/361,783 was a CIP of Application 08/186,285. One aware of Appellants' priority trail would have easily recognized that the Examiner inadvertently switched parent applications 08/186,285 and 08/361,783 in the aforementioned statement.

#### Conclusion

It is respectfully submitted that no other comments by Appellants are deemed necessary with regard to the Office Action dated December 19, 2005 (as it is best understood). The Declaration remains sufficient. A decision on appeal or allowance by the Office at this juncture is earnestly requested.

Respectfully submitted,

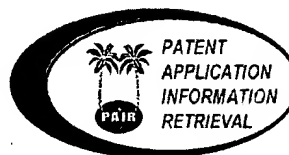


Ralph E. Jocke  
WALKER & JOCKE  
231 South Broadway  
Medina, Ohio 44256  
(330) 721-0000

Reg. No. 31,029



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**Patent Assignment Abstract of Title****Total Assignments: 3****Application #:** 09014076 **Filing Dt:** 01/27/1998**Patent #:** NONE**Issue Dt:****PCT #:** NONE**Publication #:** NONE**Pub Dt:****Inventors:** MAX A. FEDOR, ERIC R. COLBURN, ROBERT G. GILLIO, DANIEL W. NEU, R. MICHAEL MCGRADY**Title:** METHOD FOR TRACKING AND DISPENSING MEDICAL ITEMS**Assignment: 1**

<b>Reel/Frame:</b>	012447 / 0445	<b>Received:</b>	03/06/2002	<b>Recorded:</b>	03/06/2002	<b>Mailed:</b>	03/07/2002	<b>Pages:</b>	12
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**Conveyance:** CONDITIONAL ASSIGNMENT, LICENSE BACK AND SECURITY AGREEMENT**Assignor:** DIEBOLD, INCORPORATED**Exec Dt:** 07/12/2001**Assignee:** MEDECORX, INC.SUITE 300N, 5600 ROSWELL ROAD  
ATLANTA, GEORGIA 30342**Correspondent:** WALKER & JOCKE, L.P.A.RALPH E. JOCKE  
231 SOUTH BROADWAY  
MEDINA, OH 44256**Assignment: 2**

<b>Reel/Frame:</b>	014108 / 0608	<b>Received:</b>	11/10/2003	<b>Recorded:</b>	11/10/2003	<b>Mailed:</b>	11/10/2003	<b>Pages:</b>	6
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**Conveyance:** CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).**Assignor:** MEDECORX, INC.**Exec Dt:** 02/08/2002**Assignee:** MEDSELECT INC.6250 SHILOH ROAD SUITE 240  
ALPHARETTA, GEORGIA 30005**Correspondent:** RALPH E. JOCKE231 SOUTH BROADWAY  
MEDINA, OH 44256**Assignment: 3**

<b>Reel/Frame:</b>	014981 / 0737	<b>Received:</b>	02/23/2004	<b>Recorded:</b>	02/19/2004	<b>Mailed:</b>	08/16/2004	<b>Pages:</b>	5
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**Conveyance:** MERGER (SEE DOCUMENT FOR DETAILS).**Assignor:** MEDSELECT INC.**Exec Dt:** 02/02/2004**Assignee:** AUTOMED TECHNOLOGIES, INC.1300 MORRIS DRIVE, SUITE 100  
C/O AMERISOURCEBERGEN CORPORATION  
CHESTERBROOK, PENNSYLVANIA 19087**Correspondent:** DECHERT LLPMATTHEW T. SMITH  
1717 ARCH STREET  
PHILADELPHIA, PA 19103-2793

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